

claims “based on inapplicable and/or non-existent” local coverage determinations (“LCDs”)¹ “or by improperly elevating” a local coverage article (“Article”)² to the status of an LCD, in contravention of applicable law. *Id.*

Plaintiffs ask the Court to grant their “proposed TRO overturning months of knowing and willful constitutional and procedural violations by Defendants.” ECF No. 5 at 29. As part of their request, Plaintiffs ask the Court order Defendants:

to process [Plaintiffs’] pending and future claims in accordance with established lawful procedures, immediately reopening and readjudicating all denied claims in accordance with established lawful procedures, as they existed at the time the claims were submitted, or alternatively as respects denied claims, allow the denied claims to be re-submitted for proper processing by Defendants.

Id. Plaintiffs also ask for “an expedited preliminary injunction briefing [schedule]” addressing Plaintiffs’ “entitlement to an adequate administrative review process and redress for multiple constitutional and procedural violations.” *Id.*

LEGAL STANDARD

“An injunction is an extraordinary remedy and should not issue except upon a clear showing of possible irreparable injury.” *Lewis v. S.S. Baune*, 534 F.2d 1115, 1121 (5th Cir. 1976). A temporary restraining order (“TRO”) is a “highly accelerated and temporary form of preliminary injunctive relief.” *Hassani v. Napolitano*, No. 3:09-CV-1201-D, 2009 WL 2044596, at *1 (N.D. Tex. July 15, 2009). A TRO must be restricted to “preserving the status quo and preventing irreparable harm just so long as is necessary to hold a hearing, and no longer.” *Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70 of Alameda Cnty.*, 415 U.S. 423, 439 (1974).

¹ The LCDs at issue are L39063 (“Pharmaco LCD”) and L39082 (“Cardiac LCD”).

² The Article at issue is A58917.

Federal Rule of Civil Procedure 65(b) governs the issuance of a TRO. A “court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney” only if two criteria are satisfied. FED. R. CIV. P. 65(b)(1). First, the movant must provide “specific facts in an affidavit or a verified complaint clearly show[ing] that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition.” FED. R. CIV. P. 65(b)(1)(A). Second, “the movant’s attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.” FED. R. CIV. P. 65(b)(1)(B).

To obtain injunctive relief, the movant must establish: (1) a substantial likelihood that the movant will prevail on the merits; (2) a substantial threat that irreparable harm will result if the injunction is not granted; (3) that the threatened injury outweighs the threatened harm to the non-movant; and (4) that the granting of the preliminary injunction will not disserve the public interest. *Clark v. Prichard*, 812 F.2d 991, 993 (5th Cir. 1987). The movant “must satisfy a cumulative burden of proving each of the four elements enumerated before a temporary restraining order or preliminary injunction can be granted.” *Id.* If the movant fails to satisfy any one of the four factors, a TRO will not issue. *See May v. Wells Fargo Home Mortg.*, No. 3:12-CV-4597-D, 2013 WL 2367769, at *1 (N.D. Tex. May 30, 2013); *Acumen Enters., Inc. v. Morgan*, No. 3:11-CV-619-L, 2011 WL 1227781, at *3 (N.D. Tex. Mar. 29, 2011) (declining to address public-interest factor when movant could not satisfy other factors addressed).

Whether to grant a TRO “is within the discretion of the court, but it is an extraordinary remedy that should only be granted if the movant has clearly carried its burden.” *John Crane Prod. Sols., Inc. v. R2R & D, LLC*, 861 F. Supp. 2d 792, 794 (N.D. Tex. 2012); *see also White v. Carlucci*, 862 F.2d 1209, 1211 (5th Cir. 1989) (same). The decision to grant a TRO “is to be treated as the

exception rather than the rule.” *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins by addressing the procedure governing issuance of a TRO under Rule 65. The Court then turns to the four factors Plaintiffs must satisfy.

A. Plaintiffs Have Not Satisfied Rule 65(b)(1)(B)

Rule 65(b)(1)(B) requires Plaintiffs’ attorneys to certify “in writing any efforts made to give notice and the reasons why it should not be required” before the Court “may issue a temporary restraining order without written or oral notice” to Defendants.

Plaintiffs’ Verified Complaint confirms Plaintiffs and Defendant Novitas have been in contact about the alleged wrongfully denied claims since at least March 23, 2022.³ *See* ECF No. 1 at 16. Plaintiffs have been in contact with CMS since at least April 11, 2022. *See id.* at 18. Although Plaintiffs state they have notified “the local United States Attorneys’ [sic] Office and served Defendants,” they do not state whether they have been in contact with Defendants Secretary Becerra or CMS Administrator Brooks-LaSure. ECF No. 5 at 7. At the July 8, 2022 hearing, the Court asked if Plaintiffs have been in contact with Defendants. Plaintiffs stated they have served Defendants and been in contact with various Defendants for some time.⁴

Plaintiffs have not satisfied Rule 65(b)(1)(B)’s requirements. Plaintiffs have not certified “in writing any efforts made to give notice” to Defendants. FED. R. CIV. P. 65(b)(1)(B). And Plaintiffs have not provided the Court “reasons why [notice] should not be required.” *Id.*

³ Defendant Novitas is a Medicare administrative contractor (“MAC”). A MAC is a private government contractor that processes Medicare claims for CMS. *See* 42 U.S.C. § 1395kk-1; 42 C.F.R. §§ 405.904(a)(2)–405.928.

⁴ Plaintiffs have served Defendants since filing their application for TRO. *See* ECF Nos. 14–16. Defendants have not yet appeared.

Plaintiffs have instead been in contact with several Defendants for some time.⁵ Accordingly, the Court finds it inappropriate to issue an *ex parte* TRO without first hearing from Defendants.⁶ But even assuming Plaintiffs satisfied Rule 65(b)(1)(B), Plaintiffs have not demonstrated their entitlement to injunctive relief.

B. Plaintiffs Fail to Demonstrate a Substantial Threat of Irreparable Harm that the Issuance of a TRO Will Redress

Plaintiffs must show they are likely to suffer “irreparable harm.” Irreparable harm is “harm for which there is no adequate remedy at law.” *Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.*, 710 F.3d 579, 585 (5th Cir. 2013); *see also Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (same). A clear showing of irreparable harm cannot be speculative. *See Hollan Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985) (“Speculative injury is not sufficient; there must be more than an unfounded fear on the part of the applicant.”).

Plaintiffs allege they will “very likely” breach their loan covenants with their lenders in July 2022. ECF No. 5 at 6. Plaintiffs also allege such a breach “may force” them “to liquidate or file bankruptcy.” *Id.*; *see also* ECF No. 1 at 4 (same). And “if” Plaintiffs must liquidate, their “remaining employees will lose their jobs and their paychecks and the business will be ruined.” ECF No. 1 at 5. The terms “likely,” “may,” and “if” suggest Plaintiffs’ alleged harm is more

⁵ The Court credits Plaintiffs’ attempts to negotiate a solution with Defendants. And the Court recognizes that Plaintiffs’ attempts justify some delay in filing suit and pursuing injunctive relief. *See, e.g., All Tech Repairs, Inc. v. MMI-CPR, LLC*, No. 3:19-CV-1051-K, 2019 WL 2286082, at *3 (N.D. Tex. May 29, 2019). But the TRO Plaintiffs request is only an “emergency” because Plaintiffs claim they must soon lay off employees, liquidate assets, or face bankruptcy. *See id.* That is, “while the Court has no issue with Plaintiffs attempting to negotiate a resolution without litigation, Plaintiffs were aware of the harm posed” for many months before initiating this litigation. *Id.* Although the Court does not find this delay strongly weighs against the issuance of a TRO, the delay undermines the exigency of Plaintiffs’ “emergency” motion. *See id.*; *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996).

⁶ Plaintiffs have served Defendants since filing their application for TRO. *See* ECF Nos. 14–16. Defendants have not yet appeared.

speculative in nature. Yet Plaintiffs also allege these consequences are unavoidable unless the Court enjoins “Defendants’ unconstitutional conduct.” ECF No. 5 at 7.

Despite alleging Plaintiffs will suffer unavoidable consequences in the absence of injunctive relief, Plaintiffs present few facts actually demonstrating irreparable harm. Although Plaintiffs filed a roughly 700-page Appendix alongside their Motion, Plaintiffs do not direct the Court to evidence of imminent insolvency. Specifically, Plaintiffs fail to identify: (1) the exact or approximate amount of money Plaintiffs owe creditors and the terms of any credit agreements; (2) Plaintiffs’ current income streams *apart* from billing CPT codes 81401–08; (3) the income from such streams and whether that income is sufficient to meet Plaintiffs’ current debt load; (4) the portion or percentage of the 2,800 claims submitted that may no longer be reimbursed under current guidance — if any; and (5) an explanation of the changes in procedure Plaintiffs made after Defendants issued the Pharmaco LCD and Cardiac LCD. *See generally* ECF Nos. 1, 5, 21. And although Plaintiffs assert they have “already reduced staff by approximately 10 employees and absent a TRO will lay off 10 more this week,” Plaintiffs have not told the Court how many stay they employ *total*. ECF No. 21 at 4. The Court cannot determine Plaintiffs will suffer irreparable harm based on these vague allegations alone and, therefore, will not issue extraordinary relief based on those allegations.

Moreover, it is not clear that ordering Defendants to reprocess approximately 2,800 denied claims would protect Plaintiffs from an irreparable harm of imminent insolvency. Plaintiffs ask the Court to order Defendants to “immediately reopen[] and readjudicate[] all denied claims in accordance with established lawful procedures, as they existed at the time the claims were submitted.” ECF No. 5 at 29. Alternatively, Plaintiffs ask the Court to “allow the denied claims to be re-submitted for proper processing by Defendants.” *Id.*

At least two outcomes may occur if Defendants reprocess Plaintiffs' claims. First, Defendants can pay Plaintiffs' denied claims. Based on the allegations contained in Plaintiffs' pleadings, payment is the only relief that can ultimately protect Plaintiffs from liquidation and bankruptcy. Second, Defendants can again deny Plaintiffs already denied claims. The latter result would do nothing to help Plaintiffs.

The only way the requested TRO Plaintiffs seek can prevent the harm alleged is if Defendants pay Plaintiffs' denied claims. Of course, Plaintiffs cannot ask the Court to order Defendants to pay the denied claims. *See Heckler v. Ringer*, 466 U.S. 602, 614 (1984) ("It seems to us that it makes no sense to construe the claims of those three respondents as anything more than, at bottom, a claim that they should be paid for their BCBR surgery."). Such relief would likely be procedural — as opposed to substantive — and moot Plaintiffs' collateral-claims exception argument.⁷ *See id.* So, Plaintiffs appear to ask the Court to order Defendants to reevaluate the denied claims in a way that *presumably* leads to payment.⁸ Reprocessing without payment would not protect Plaintiffs from the harms they allege.⁹

⁷ Plaintiffs admit they have not exhausted all available administrative remedies. *See* ECF No. 5 at 21–25. But Plaintiffs argue the threat of bankruptcy entitles them to avoid administrative exhaustion requirements by way of the collateral-claim exception. *Id.* The Court does not address whether the exception applies, and will await fulsome briefing from all parties before ruling on the application of the exception.

⁸ "It is the threat of harm that cannot be undone which authorizes exercise of [a court's] equitable power to enjoin before the merits are fully determined." *Parks v. Dunlop*, 517 F.2d 785, 787 (5th Cir. 1975) (per curiam). The possibility of a damages award often precludes a finding of irreparable harm sufficient to authorize injunctive relief. *See United States v. Hayes Int'l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969). The Court notes an exception to this general rule exists when withholding relief "would have entailed the virtual disappearance of" the plaintiff "as a functional entity." *Henry v. First Nat'l Bank of Clarksdale*, 595 F.2d 291, 305 (5th Cir. 1979); *see also Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.*, 875 F.2d 1174, 1179 (5th Cir. 1989) (stating irreparable harm exists when "potential economic loss is so great as to threaten the existence of the movant's business").

⁹ Plaintiffs do not provide the Court with a breakdown of what *categories* of claims were denied by Novitas pursuant to the challenged application of the LCDs and Articles in question (*e.g.*, neuro claims, cardio claims, obesity or diabetic claims, or cancer claims). At the July 8, 2022 hearing, Plaintiffs stated the majority of the denied claims were cardiac claims, and the Cardiac LCD may well apply to such claims. (As Plaintiffs acknowledged, some of their claims were properly denied under this new LCD and Plaintiffs made changes to procedures as a result.) Plaintiffs' concessions undermine their request for TRO or injunctive relief. Plaintiffs assert Defendant Novitas automatically and reflexively denies CPT codes 81401–08 following the issuance of the Cardiac LCD and the Pharmacology LCD. However, the automatic application of these LCDs to these CPT codes appears to have resulted in the proper denial of claims in

This raises the question: Can the Court issue a TRO requiring Defendants to reprocess Plaintiffs’ denied claims (in a fashion presumably leading to payment) when those claims may have been properly denied in the first instance? Plaintiffs’ briefing argues in the affirmative. In support of that argument, Plaintiffs cite several cases. *See, e.g., Med-Cert Home Care, LLC v. Azar*, 365 F. Supp. 3d 742 (N.D. Tex. 2019); *Angels of Care Home Health, Inc. v. Azar*, No. 18-CV-3268, 2019 WL 1101286 (N.D. Tex. Feb. 13, 2019); *Adams EMS, Inc. v. Azar*, No. H-18-1443, 2018 WL 5264244 (S.D. Tex. Oct. 23, 2018); *Family Rehab., Inc. v. Azar*, No. 17-CV-2018, 2018 WL 3155911 (N.D. Tex. June 28, 2018).

In *Med-Cert Home Care*, the defendants determined they overpaid Medicare claims submitted by the plaintiff. 365 F. Supp. 3d at 746. The defendants therefore sought to recoup the overpayments from the plaintiff by withholding Medicare reimbursement payments on current and future claims. *Id.* at 747–48. The defendants did not dispute the validity of the claims on which they sought to withhold payment. *See id.* at 749–750. Indeed, that would have defeated the recoupment scheme, as one cannot recoup payment from a denied claim. The defendants instead argued the plaintiff had “no valid property interest at risk of erroneous deprivation” because the plaintiff could not “claim a property interest in the recoupment of an overpayment determination.” *Id.* at 750. The plaintiff disagreed and asserted a property interest in the Medicare payments. *Id.* The plaintiff also asserted a high risk of an erroneous deprivation of that property interest because the plaintiff would likely go out of business before resolution of the payment dispute. *Id.* The injunctive relief granted in *Med-Cert Home Care* required the defendants to pay on the plaintiffs’ claims, which all parties acknowledged as valid. *Id.* at 759. In this case, by contrast, Plaintiffs

some instances. The information provided to the Court fails to indicate how this Court — without addressing the merits of Plaintiffs’ claims — could enjoin the application of the Cardiac and Pharmaco LCDs to Plaintiffs’ Medicare claims.

cannot assert a property interest in the denied claims. Whereas the *Med-Cert Home Care* plaintiff had valid claims on which the defendants refused to pay, the parties to the instant case *dispute* the validity of Plaintiffs' claims. *See id.* at 751 ("Precedent makes clear that Med-Cert has a valid property interest in receiving Medicare payments for services rendered."). *But see Infinity Healthcare Servs., Inc. v. Azar*, 349 F. Supp. 3d 587, 596 (S.D. Tex. 2018) ("Antithetically, [a plaintiff] does not 'have a property interest in a level of benefits that is greater than Congress has provided.' . . . [A plaintiff's] property interest is circumscribed by the merits of its claim to Medicare payments." (quoting *Sahara Health Care, Inc. v. Azar*, 349 F. Supp. 3d 555, 572 (S.D. Tex. 2018))).

To avoid bankruptcy, the plaintiff in *Angels of Care Home Health* also sought to enjoin the defendant from withholding payment on valid Medicare claims pending administrative resolution of a recoupment dispute. 2019 WL 1101286, at *1–2. Like *Med-Cert Home Care*, the *Angels of Care Home Health* plaintiff held a property interest in payment for valid Medicare claims that the government sought to recoup by withholding payment on valid claims. *Id.* at *3. In the *Adams EMS* case, when the defendants sought to recoup overpayment from the plaintiff, the court recognized a property interest in payment for valid Medicare claims. 2018 WL 5264244, at *1. And a property interest in payment for valid Medicare claims was also at issue in *Family Rehab.* 2018 WL 3155911, at *4. As in the other cases cited by Plaintiffs, the court enjoined defendants from halting valid Medicare claim payments in order to recoup funds from the plaintiff absent procedural due-process guarantees. *Id.* at *7. *But see Sahara Health Care*, 349 F. Supp. 3d at 572 (holding contrary to aforementioned cases).

This case is distinguishable from the recoupment cases. The plaintiffs in the recoupment cases held established property interests in properly billed, valid claims.¹⁰ The defendants sought to withhold payment on those valid claims to compensate for alleged overpayments. Here, by contrast, Plaintiffs have not established a property interest in the claims Defendants denied. In the instant case, Defendants will presumably challenge the validity of the disputed claims; in the recoupment cases, the defendants did *not* challenge the validity of the disputed claims.

Without a “property interest, there can be no due process violation.” *Sahara Health Care*, 349 F. Supp. 3d at 571. “A property interest requires ‘more than a unilateral expectation’ of a benefit.” *Personal Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 158 (5th Cir. 2011) (quoting *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972)); *see also Koerpel v. Heckler*, 797 F.2d 858, 863 (10th Cir. 1986) (“A mere expectation of entitlement is insufficient to create a property right.”). Instead, one “must have a legitimate claim of entitlement to” the benefit. *Roth*, 408 U.S. at 577. Standing alone, Plaintiffs’ “participation in the Medicare program and related appeals process does not equate to having a property interest in [their] reimbursement claims.” *Sahara Health Care*, 349 F. Supp. 3d at 572; *see also Acute Care Ambulance Serv., L.L.C. v. Azar II*, No. 7:20-CV-217, 2020 WL 7640206, at *9 (S.D. Tex. Dec. 3, 2020) (“The writing on the wall seems clear: there is no property interest in Medicare payments.”).

At this point in the litigation, Plaintiffs have not shown a “reasonable expectation or entitlement to be paid on a . . . denied claim for reimbursement.” *Sahara Health Care*, 349 F. Supp. 3d at 572; *cf. Smith v. N. La. Med. Review Ass’n*, 735 F.2d 168, 174 (5th Cir. 1984) (“[A] provider has no reasonable expectation or entitlement to be paid on a bad claim, that is a claim not covered

¹⁰ *See* U.S. CONST. amend. V (“No person shall be . . . deprived of life, liberty, or property, without due process of law.”); Property Interest, BLACK’S LAW DICTIONARY (11th ed. 2019) (“*Constitutional law*. A legitimate claim of entitlement to some legal or contractual benefit that cannot be taken away without due process.”).

under the [Medicare] Act.”); *Personal Care Prods., Inc. v. Hawkins*, No. A-07-CA-1020-LY, 2009 WL 2406253, at *8 (W.D. Tex. Aug. 2009), *report and recommendation adopted*, 2009 WL 7472394 (W.D. Tex. Aug. 18, 2009) (“In this case, Plaintiffs have not demonstrated a legitimate claim of entitlement to the withheld payments.”). And again, if Plaintiffs are not entitled to payment for the disputed claims, then a TRO requiring the reprocessing of Plaintiffs’ denied claims would do nothing to prevent the harm Plaintiffs allege they may suffer.

In sum, Plaintiffs have not shown: (1) the imminency of the alleged irreparable harm through factual development; (2) injunctive relief would redress the alleged harm; and (3) a property interest in reimbursement for the denied claims. Accordingly, the Court finds Plaintiffs have not alleged a substantial threat of irreparable harm redressable by the TRO they request.

C. Plaintiffs Fail to Demonstrate a Substantial Likelihood of Success on the Merits

Because the Court determined the issuance of a TRO to be improper, the Court need not address Plaintiffs’ likelihood of success on the merits. *See May*, 2013 WL 2367769, at *1. But the Court would also deny Plaintiffs a TRO based on this factor.

Plaintiffs allege two “processing error” claims: (1) Defendant Novitas applies inapplicable LCDs to CPT codes 81401–08; and (2) Defendants “elevated” Article A58917 to the status of an LCD without the notice-and-comment period that accompanies the issuance of an LCD. *See generally* ECF Nos. 1, 5. The Court addresses each argument in turn.

First, Plaintiffs argue Defendant Novitas applied the Pharmacogenomic and Cardiac LCDs to all of its claims under CPT codes 81401–08. *See id.* at 14–15. Plaintiffs assert the Pharmacogenomic LCD is limited to pharmacogenomic claims and the Cardiac LCD is limited to cardiac claims. *Id.* Plaintiffs aver Defendant Novitas uses these LCDs to deny claims under CPT codes 81401–08 involving *genetic* testing for neurological disorders, cancer gene identification, as well as diabetic

and obesity gene testing. *Id.* Plaintiffs claim the limited scope of these LCDs does not provide notice to Medicare providers that these LCDs would apply to all claims under these CPT codes. *Id.* This — Plaintiffs argue — resulted in denials under LCDs without a notice-and-comment period that would allow providers to challenge this application. *Id.*

Plaintiffs, however, have not established whether Defendant Novitas improperly applied the Pharmaco and Cardiac LCDs. To the contrary: Plaintiffs acknowledge some claims submitted under CPT codes 81401–08 were properly denied in accordance with the Pharmaco and Cardiac LCDs. Accordingly, the Court is reluctant to evaluate whether the application of these LCDs was in fact improper. In making such a determination, the Court would likely need to conduct claim-by-claim analysis, and such an analysis becomes appropriate only after Plaintiffs exhaust applicable administrative remedies. *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 501–02 (5th Cir. 2018).

Second, Plaintiffs argue Defendants “elevated” Article A58917 to the status of an LCD without the notice-and-comment period that accompanies the issuance of an LCD. ECF No. 1 at 19–20. Plaintiffs assert Article A58917 is inapplicable to the disputed claims, does not apply to either the Cardiac LCD or the Pharmaco LCD, and is improperly treated as controlling authority with respect to claim denials.

Plaintiffs have — at most — weak evidence indicating Defendant Novitas originally applied Article A58917 when evaluating Plaintiffs’ claims, or that Defendant Novitas regularly does so as a matter of policy. Plaintiffs refer the Court to an April 13, 2022 email from Patricia Reidenbach, a research analysis for Defendant Novitas. *See* ECF No. 6-3 at 243–45. That email is the only evidence Plaintiffs have identified to support their argument that Defendant Novitas relied on Article A58917. But the claim denials issued by Defendant Novitas do not reference Article

A58917. *See, e.g.*, ECF No. 7 at 27, 30, 33. Indeed, Plaintiffs did not know Article A58917 allegedly impacted their denied claims until receiving Reidenbach's email.

More importantly, Plaintiffs misconstrue *how* Article A58917 was used here. Plaintiffs present no evidence that Article A58917 was invoked to *categorically* deny reimbursement to an entire "group" of genetic tests authorized by LCD — only that Defendant Novitas cited Article A58917 as *persuasive* authority for requiring Plaintiffs prove an individual genetic test within said "group" is "reasonable and necessary." This is not an inappropriate use of an Article under the Medicare statutes, the Cures Act, or the *Finnegan* opinion. Even Plaintiffs acknowledge that each CPT code in question can encompass a "group" of several individual tests. ECF No. 21 at 5–6. Thus, some genetic testing billed under these CPT codes may require more information for full adjudication.

Article A58917 is labeled "Billing and Coding: Molecular Pathology and Genetic Testing." Article A58917 states "[a]dvanced diagnostic laboratory tests must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests." And Article A58917 further provides:

Many applications of the molecular pathology procedures are not covered services given a lack of benefit category (*e.g.*, preventive service or screening for a genetic abnormality in the absence of a suspicion of disease) and/or failure to meet the medically reasonable and necessary threshold for coverage (*e.g.*, based on quality of clinical evidence and strength of recommendation or when the results would not reasonably be used in the management of a beneficiary)

The Court thus reads Article A58917 to apply to Medicare's overarching mandate that all laboratory testing must be "reasonable and necessary." *See* 42 U.S.C. § 1395 *et seq.*

Plaintiffs provide no authority to support the proposition that only Articles of the same name as an LCD can apply to that LCD. Moreover, Plaintiffs argue that — for the vast majority of their denied claims — no LCD exists to process these claims. *See* ECF No. 1 at 11. It does not

follow that no Article can assist a MAC in determining how to adjudicate CPT codes that do not fall under a particular LCD, and the Court is unaware of any authority stating as much.

Article A58917 provides:

[T]he updates to CPT since 2013 have NOT resulted in the elimination or reduction of stacking of codes in billing. Rather the billing of multiple CPT codes for a unique molecular pathology or genetic test has significantly increased over the last two (2) years. Coding issues have been identified throughout all the molecular pathology coding subgroups, but these issues of billing multiple CPT codes for a specific test have been significant in the Tier 2 (81403 - 81408) and Not Otherwise Classified (81479) codes. Per Title 42 of the United States Code (USC) Section 1320c-5(a)(3), providers are required by law to “provide economical medical services and then, only where medically necessary.” In keeping with Title 42 of the USC Section 1320c-5(a)(3), claims inappropriately billed utilizing stacking or unbundling of services will be rejected or denied.

Article A58917 addresses “stacking” CPT codes — codes 81403–08 — often used by healthcare providers and laboratories to order group tests designed to identify multiple genes without identifying how *all* of the tests *within* the group are medically necessary.

Plaintiffs also misconstrue a MAC’s authority to issue an Article. Plaintiffs argue that, because Article A58917 was not issued to address a specific LCD, the Article creates substantive decision guidance on eligibility regarding CPT billing codes without undergoing any notice-and-comment procedure, as would be required of an LCD. ECF No. 1 at 19–21. Yet notice and comment is required only when an LCD, not an Article, is issued. *See* 21st Century Cures Act of 2016, Pub. L. No. 114–255, 130 Stat. 1033. That is because only an LCD, not an Article, can make a coverage determination. *See id.*

Article A58917 does not appear to limit coverage of any particular test, even if it affects procedures regarding certain billing codes. Rather, Article A58917 addresses the “stacking” of tests without addressing whether such tests are “reasonable and necessary.” Article A85917 does not appear to prohibit certain tests; it only appears to address when such tests may be billed as a group. It therefore makes sense that Article A58917 is a “billing and coding” Article not associated

with any particular LCD. Article A58917 appears to explain billing procedures, not coverage. Plaintiffs have not provided the Court with authority indicating that such an Article is impermissible.


Based on the foregoing, the Court is skeptical of Plaintiffs' Article-promulgation arguments. Plaintiffs have not shown a substantial likelihood of success on the merits as of this stage of the litigation. Accordingly, this factor weighs against the issuance of a TRO.¹¹

CONCLUSION

Because Plaintiffs have not satisfied Rule 65(b)(1)(B)'s requirements, demonstrated an irreparable injury, or shown a substantial likelihood of success on the merits, the Court **DENIES** Plaintiffs' Motion.

SO ORDERED.

July 11, 2022.


MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE

¹¹ The Court again notes, even if Plaintiffs were likely to succeed on the merits, it is possible the relief sought may do nothing to save Plaintiffs from bankruptcy.